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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 06/04/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | |
|--------------------------------------|------------------------------------|
| Application No. 09/630,454 | Applicant(s) Liaw Wt Al. |
| Examiner S. Devi, Ph.D. | Art Unit 1645 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Apr 4, 2003

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-23 is/are pending in the application.

4a) Of the above, claim(s) 1-5 and 17-23 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 6-16 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) Other: _____

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' amendment filed 04/04/03 (paper no. 11) in response to the non-final Office Action mailed 11/05/02 (paper no. 9).

Status of Claims

- 2) Claims 1-23 are pending.

Claims 1-5 and 17-23 are withdrawn from consideration as being directed to non-elected inventions. See 37 C.F.R. 1.142(b) and M.P.E.P. § 821.03. Claim 10 encompassing a non-elected species is currently withdrawn from consideration.

Claims 6-16 have been elected.

Claims 6-9 and 11-16 are under examination. A First Action on the Merits is issued for these claims.

Prior Citation of Title 35 Sections

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

- 5) The objection to the specification made in paragraph 6 of the Office Action mailed 11/05/02 (paper no. 9) is withdrawn in light of Applicants' amendment to the specification.

Rejection(s) Withdrawn

- 6) The rejection claim 7 made in paragraph 8(a) of the Office Action mailed 11/05/02 (paper no. 9) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 7) The rejection claim 11 in paragraph 8(b) of the Office Action mailed 11/05/02 (paper no. 9) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

- 8) The rejection claim 11 made in paragraph 8(b) of the Office Action mailed 11/05/02 (paper no. 9) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 9) The rejection claim 9 made in paragraph 8(c) of the Office Action mailed 11/05/02 (paper no. 9) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 10) The rejection claim 6 made in paragraph 8(d) of the Office Action mailed 11/05/02 (paper no. 9) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 11) The rejection claim 6 made in paragraph 8(e) of the Office Action mailed 11/05/02 (paper no. 9) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 12) The rejection claim 9 made in paragraph 8(f) of the Office Action mailed 11/05/02 (paper no. 9) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 13) The rejection claim 11 made in paragraph 8(g) of the Office Action mailed 11/05/02 (paper no. 9) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 14) The rejection claims 8 and 12-16 made in paragraph 8(h) of the Office Action mailed 11/05/02 (paper no. 9) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims and/or the base claim(s).
- 15) The provisional rejection claims 6-8 made in paragraph 9 of the Office Action mailed 11/05/02 (paper no. 9) under the judicially created doctrine of obviousness-type double patenting as being patentable over claims 20, 21-26, 29, 30, 49-52, 54, 57 and 58 of the co-pending application, SN 09/962,303 (not 08/962,303), is withdrawn upon further consideration.
- 16) The rejection claims 6-8 made in paragraph 9 of the Office Action mailed 11/05/02 (paper no. 9) under the judicially created doctrine of obviousness-type double patenting as being patentable over claims 1-12 of the US patent 5,939,307, is withdrawn upon further consideration.
- 17) The rejection claims 6-8 made in paragraph 11 of the Office Action mailed 11/05/02 (paper

no. 9) under 35 U.S.C. § 102(b) as being anticipated by Sahm et al. (*Ann. N.Y. Acad. Sci.* 782: 25-39, 1996 - Applicants' IDS), is withdrawn in light of Applicants' amendment to the claims and/or the base claim(s).

Rejection(s) Maintained

18) The rejection claims 11-16 made in paragraph 7 of the Office Action mailed 11/05/02 (paper no. 9) under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure, with regard to the deposit issue, is maintained for reasons set forth therein and herebelow.

Applicants provide copies of the deposit notices from the depository showing acceptance of the recited strains by the depository, the depository accession numbers given the strains, and establishing that the deposited bacterial strains are the same as the ones described in the specification and that the deposited bacterial strains were in Applicant's possession at the time of filing. A statement has been provided by Applicants' attorney stating that all restrictions on the availability of the deposited strains to the public will be irrevocably removed upon the granting of a patent. However, the specification does not fully comply with the deposit rules 37 C.F.R. § 1.801-1.809. For example, the name and full address of the depository where the recited strains have been deposited and the date the deposition was made are missing from the instant specification. See 37 C.F.R. § 1.807 (b).

Rejection(s) under 35 U.S.C. § 101

19) 35 U.S.C. § 101 states:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this cycle.

20) Claims 6-8 are rejected under 35 U.S.C. § 101 as being directed to a non-statutory subject matter.

Instant claims, as written, do not sufficiently distinguish over a bacterial strain, as it exists naturally, i.e., a natural mutant, because the claims do not particularly point out any non-naturally occurring differences between the claimed product and the naturally occurring product. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject

matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claim(s) should be amended to indicate the hand of the inventor, e.g., by insertion of 'An isolated' as described in the specification. See MPEP 2105.

Rejection(s) under 35 U.S.C § 112, First Paragraph

21) Claims 6-8 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The limitation in the base claim: 'impaired' raffinate resistance does not have descriptive support in the specification. Applicants point to page 5, lines 12-13 and 22-28 and page 8, lines 11-12 as providing support for the new limitation(s). However, these parts of the specification do not describe 'impaired' raffinate resistance. Therefore, the limitation in the claim(s) is considered to be new matter. An amendment to a claim must have antecedent basis in the original disclosure. See 37 CFR 1.121. MPEP 2163.06 states that Applicants should specifically point out the support for any amendments made to the disclosure. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are requested to remove the new matter from the claim(s), or point to the page and line number in the specification where support for such a recitation can be found.

Rejection(s) under 35 U.S.C § 102

22) Claims 6-8 are rejected under 35 U.S.C. § 102(b) as being anticipated by Shijo *et al.* (US 5,077,207).

Shijo *et al.* disclosed a bacterial strain, for example, a *Brevibacterium* sps. that produces an amino acid, such as, threonine, wherein the strain was obtained from a parent strain. The parent strain was grown in a culture medium containing ammonium sulfate, salts, a carbohydrate such as glucose, L-histidine and soybean hydrolysate, and a mutant resistant strain was selected which overproduced or exhibited maximum production of the amino acid compared to the parent strain (see Examples 1 and 2; Table 3; last paragraph in column 4). That the prior art culture medium contains

at least 1% raffinate as described on page 7, lines 4-6 of the specification is inherent from the teachings of Shijo *et al.* since it includes ammonia sulfate, an amino acid such as L-histidine, salts, a carbohydrate such as glucose, and other amino acids and/or carbohydrates intrinsically present in soybean hydrolysate. That the mutant bacterial strain had an impaired raffinate resistance compared to the parent strain is also inherent from the results obtained by Shijo *et al.*

Claims 6-8 are anticipated by Shijo *et al.*

23) Claim 9 is rejected under 35 U.S.C. § 102(b) as being anticipated by Nakanishi *et al.* (US 4,657,860).

Nakanishi *et al.* disclosed a *Corynebacterium* strain which produces about 34 to 36 g/l of L-lysine in 24 hours when grown in a bacterial culture medium containing at least 1% raffinate, i.e., glucose, ammonium sulfate, various salts, and soybean meal (inclusive of amino acids). See Example 2 and Table 2.

Claim 9 is anticipated by Nakanishi *et al.*

24) Claims 6-8 are rejected under 35 U.S.C. § 102(b) as being anticipated by Sano *et al.* (US 4,436,170).

Sano *et al.* taught an *E. coli* strain which overproduces L-lysine (see column 2, first full paragraph). The lysine-producing transformant (i.e., mutant) is obtained from a parent recipient which was rendered auxotrophic to L-lysine, i.e., mutagenized (see paragraph bridging columns 2 and 3). The transformant is obtained by growing in a culture medium containing amino acids or casamino acid; glucose, sucrose or lactose; various salts; molasses and ammonium salts (see first and last full paragraphs in column 3). The medium contains ammonium sulfate (see paragraph bridging columns 4 and 5). The selection of L-lysine-producing mutants or transformants growing in the culture medium (i.e., those with impaired raffinate resistance) is taught (see last half of column 4). The transformant produced 28 mg/dl of L-lysine compared to 16 mg/dl produced by the parent strain (see Table in column 5). That the prior art culture medium contains at least 1% raffinate as described on page 7, lines 4-6 of the specification is inherent from the teachings of Sano *et al.* since it includes ammonia sulfate, amino acids, various salts, a carbohydrate such as glucose, sucrose or lactose.

Claims 6-8 are anticipated by Sano *et al.*

Remarks

25) Claims 6-16 stand rejected.

26) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

27) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June, 2003


S. DEVI, PH.D.
PRIMARY EXAMINER